AUSTRALIAN PRODUCT INFORMATION

SERC®

Betahistine dihydrochloride tablets

1 NAME OF THE MEDICINE

Betahistine dihydrochloride

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 8 mg or 16 mg of betahistine dihydrochloride as the active ingredient.

For the full list of excipients, see Section 6.1 LIST OF EXCIPIENTS.

3 PHARMACEUTICAL FORM

SERC (betahistine dihydrochloride) 16 mg tablets: round, biconvex, scored, white to almost white tablet with bevelled edges, one side inscribed with '267' on either side of the score.

SERC (betahistine dihydrochloride) 8 mg tablets: round, flat, white to almost white tablet with bevelled edges, one side inscribed with '256'.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Meniere's Syndrome as defined by the following core symptoms:

- vertigo (with nausea/vomiting)
- hearing loss (hardness of hearing)
- tinnitus

4.2 DOSE AND METHOD OF ADMINISTRATION

The recommended starting dose in adults is 8 to 16 mg three times a day. The maximum recommended daily dose is 48 mg.

The tablets may be taken with or without food. However, if gastrointestinal upset occurs, it is recommended that the tablets be taken with meals.

The dosage should be individually adapted according to the response. Improvement in symptoms may be observed in the first few days to weeks of treatment.

4.3 CONTRAINDICATIONS

SERC (betahistine dihydrochloride) Tablets are contraindicated as follows:

- during pregnancy and lactation.
- in children less than 18 years.
- in patients suffering from phaeochromocytoma.
- in patients with active peptic ulcer or a history of this condition.
- in patients with hypersensitivity to any component to the product (see Section 2 QUALITATIVE AND QUANTITATIVE COMPOSITION and Section 6.1 LIST OF EXCIPIENTS).

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Patients with bronchial asthma need to be carefully monitored during therapy.

Caution should be taken in the treatment of patients receiving antihistamines (see Section 4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS).

Use in the Elderly

No data available.

Paediatric Use

Due to lack of clinical experience, betahistine dihydrochloride should not be used in children less than 18 years (see Section 4.3 CONTRAINDICATIONS).

Effects on Laboratory Tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

In vitro data indicate an inhibition of betahistine metabolism by drugs that inhibit monoamine-oxidase (MAO) including MAO subtype B (e.g. selegiline). Caution is recommended when using betahistine and MAO inhibitors (including MAO-B selective) concomitantly.

An antagonism between SERC and antihistamines could be expected on a theoretical basis. However, no such interactions have been reported.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on Fertility

There are no animal data on the effects of betahistine on fertility.

Use in Pregnancy

Pregnancy category: B2

Betahistine dihydrochloride must not be used during pregnancy (see Section 4.3 CONTRAINDICATIONS) since there are insufficient data on the use of this medicine during pregnancy to evaluate possible harmful effects.

Use in Lactation

Betahistine dihydrochloride must not be used during lactation (see Section 4.3 CONTRAINDICATIONS).

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Betahistine is indicated for Ménière's syndrome defined by the triad of core symptoms vertigo, hearing loss and tinnitus which can negatively affect the ability to drive and use machines. In a clinical study (12 healthy volunteers) specifically designed to investigate the ability to drive, betahistine had no or negligible effects compared to placebo.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Most of the reported adverse reactions pertain to the skin, gastrointestinal tract, body as a whole, nervous system, respiratory system and cardiovascular system.

Events are listed within body systems and categorised by frequency according to the following definitions: very common (>1/10), Common (frequency ≥1 and <10 %), Uncommon (frequency ≥ 0.1% and < 1 %), Rare (frequency ≥ 0.01% and < 0.1 %), Very rare (frequency < 0.01 %)

Skin and subcutaneous tissue disorders:	*Rare*: various types of rash, pruritis and urticaria/angioneurotic oedema. These reactions are probably related to the histamine like structure of betahistine.

	There was a single case of Stevens-Johnson syndrome.
Body as a whole:	*Rare:* tiredness and malaise.
Gastrointestinal system:	*Common:* nausea and dyspepsia. *Rare:* vomiting, diarrhoea, abdominal distension, bloating and epigastric pain have been reported. These symptoms were usually mild. Gastrointestinal disturbances may be relieved by reducing the dose or by taking betahistine with meals.
Nervous system:	*Common*: headache. *Rare:* dizziness. *Very rare:* convulsions, somnolence, confusion and hallucinations. Some of these symptoms may also be observed as part of the disease condition and are usually resolved without changes to the treatment schedule. Patients with neurological events usually presented with confounding factors.
Cardiovascular system:	*Very rare*: vasodilation, postural hypotension and tachycardia.
Respiratory system:	*Very rare:* dyspnoea, asthma and bronchospasms (see Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE).
Immune system disorders	Hypersensitivity reactions, e.g. anaphylaxis, have been reported.

Reporting Suspected Adverse Effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

There have been a few cases of overdosage reported. Although in most cases no overdose symptoms were reported, some patients have experienced mild to moderate symptoms of overdosage including nausea, dry mouth, epigastric pain and sleepiness at doses above 200 mg. A case of convulsion was reported at a dose of 728 mg. In all cases recovery was complete. Treatment should include standard supportive measures.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of Action

The mechanism of action of betahistine is not known. Pharmacological testing in animals has shown that the blood circulation in the striae vascularis of the inner ear improves, probably by means of a relaxation of the precapillary sphincters of the microcirculation of the inner ear.

In further animal pharmacological studies, betahistine was found to have weak H1 receptor agonistic and considerable H3 antagonistic properties in the CNS and autonomic nervous system. Betahistine was also found to have a dose dependent inhibiting effect on spike generation of neurons in lateral and medial vestibular nuclei in cats. The importance of this observation in the action against Ménière's syndrome or vestibular vertigo, however, remains unclear.

Clinical Trials

No data available

5.2 PHARMACOKINETIC PROPERTIES

Absorption

In man, orally administered doses of betahistine dihydrochloride are rapidly and completely absorbed from the gastrointestinal tract.

Metabolism

The drug is rapidly metabolised to one major metabolite - 2-pyridylacetic acid

Excretion

Urinary excretion of the label was about 90% complete within 24 hours of administration. Studies with radio-labelled betahistine have demonstrated a plasma half-life of 3.4 hours and a urinary half-life of 3.5 hours for the radio-label.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data are available on the mutagenic potential of betahistine.

Carcinogenicity

No animal data are available on the carcinogenic potential of betahistine.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

SERC (betahistine dihydrochloride) is available as 8 mg and 16 mg uncoated tablets. The inactive ingredients in SERC tablets are colloidal anhydrous silica, microcrystalline cellulose, mannitol, citric acid monohydrate, and purified talc.

6.2 INCOMPATIBILITIES

Refer to Section 4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30°C.

6.5 NATURE AND CONTENTS OF CONTAINER

8 mg: PVC/PVDC/aluminium blister packs containing 10 tablets and 120 tablets.

16 mg: PVC/PVDC/aluminium blister packs containing 10 tablets (sample pack), 25 tablets and 100 tablets

Some strengths, pack sizes and/or pack types may not be marketed.

Australian Register of Therapeutic Goods (ARTG)

AUST R 61687 – SERC betahistine dihydrochloride 16 mg tablet blister pack

AUST R 61688 – SERC betahistine dihydrochloride 8 mg tablet blister pack

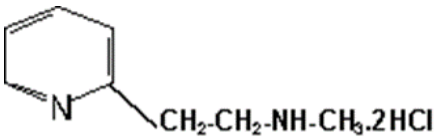
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking it to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Betahistine dihydrochloride is a white to almost white crystalline powder, which is very hygroscopic. The product is very soluble in water, freely soluble in methanol and 96% ethanol, and slightly soluble in isopropanol. The pKa values are 3.5 and 9.7.

Chemical Structure



betahistine dihydrochloride

Chemical Formula

Betahistine dihydrochloride is chemically identified as 2-[2-(methylamino)ethyl]pyridine dihydrochloride. Chemically, betahistine has a close resemblance to histamine.

Molecular Weight

209.1

CAS Number

5579-84-0

7 MEDICINE SCHEDULE (POISONS STANDARD)

S4 (Prescription Only Medicine)

8 SPONSOR

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9 DATE OF FIRST APPROVAL

SERC 16 mg: 05/11/1997

SERC 8 mg: 05/11/1997

10 DATE OF REVISION

05/10/2022

Summary Table of Changes

Section Changed	Summary of New Information
4.6, 5.3	Editorial changes to improve clarity

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